UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/944,850	10/06/97	WALT D	TU-97-01

EXAMINER	
HANNAHER, C	
ART UNIT	PAPER NUMBER
2878	

DATE MAILED: 11/05/01

MMC2/1105

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	08/944,850	WALT ET AL.	
	Examiner	Art Unit	
	Constantine Hannaher	2878	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *28,31* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

1. Where the IDS citations are submitted but not described, the examiner is only responsible for cursorily reviewing the references. The initials of the examiner on the PTO-1449 indicate only that degree of review unless the reference is either applied against the claims, or discussed by the examiner as pertinent art of interest, in a subsequent office action. See Guidelines for Reexamination of Cases in View of *In re Portola Packaging, Inc.*, 110 F.3d 786, 42 USPQ2d 1295 (Fed. Cir. 1997), 64 FR at 15347, 1223 Off. Gaz. Pat. Office at 125 (response to comment 6). Consideration by the examiner of the information submitted in an IDS means that the examiner will consider the documents in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. The initials of the examiner placed adjacent to the citations on the PTO-1449 or PTO/SB/08A and 08B or its equivalent mean that the information has been considered by the examiner to the extent noted above. MPEP § 609 (Eighth Edition, August 2001).

2. The information disclosure statement filed June 18, 2001 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Although two copies of US6083763A are provided, none is found for WO0048000A1.

3. As set forth in MPEP § 609:

> 37 CFR 1.98(b) requires that each U.S. patent listed in an information disclosure statement be identified by patentee, patent number, and issue date. Each foreign patent or published foreign patent application must be identified by the

> country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application. Each publication must be identified by author (if any), title, relevant pages of the publication, date and place of publication. The date of publication supplied must include at least the month and year of publication, except that the year of publication (without the month) will be accepted if the applicant points out in the information disclosure statement that the year of publication is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the particular month of publication is not in issue. The place of publication refers to the name of the journal, magazine, or other publication in which the information being submitted was published.

By now, applicant's representative is familiar with this statement from the MPEP. It is found as paragraph 2 of the Office action mailed February 28, 2001 and as paragraph 2 of the Office action mailed April 12, 2000. Applicant's representative has even applied the indicated procedure in the information disclosure statement submitted June 18, 2001. So it is a surprise that the information disclosure statement submitted September 4, 2001 should attempt to identify a publication by only its year of publication without using the procedure.

Note that applicant's representative is unable to identify the kind code correctly in at least one instance even when it is plainly printed on the face of the document. Note the submission of documents not available to the Examiner under any section of 35 U.S.C. 102.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 39, 40, 43-45, 47, and 48 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Pinkel *et al.* (US005690894A).

With respect to independent claim 39, Pinkel *et al.* discloses an assay method corresponding to the disclosed apparatus (Fig. **4**) which comprises a sensor array **14** having at least two subpopulations (the groups of strands **10**) of different sensor elements (sensor ends **11**, where each group may have a different sensor, column 8, lines 50-67). The assay method would comprise the steps of providing the sensor array **14**, adding a sample **30** comprising a first target analyte that binds to the first sensor elements (*e.g.*, first collection **25**), measuring a first fluorescence signal of a first of the first sensor elements **11** and a second fluorescent signal of a second of the first sensor elements **11** (column 13, lines 33-39) with detector **20**, and summing the first fluorescence signals (column 9, lines 12-14 and 21-25).

With respect to dependent claim 40, the method suggested by Pinkel *et al.* further comprises adding a sample **30** comprising a second target analyte that binds to the second sensor elements (*e.g.*, second collection **26**), measuring a third fluorescence signal of a first of the second sensor elements **11** and a fourth fluorescent signal of a second of the second sensor elements **11** (column 13, lines 33-39) with detector **20**, and summing the second fluorescence signals (column 9, lines 12-14 and 21-25).

With respect to dependent claim 43, the sensor elements (ends **11**) in the method of Pinkel *et al.* comprise chemical functional groups (column 10, lines 28-34).

With respect to dependent claim 44, the sensor elements (ends **11**) in the method of Pinkel *et al.* may comprise oligonucleotides in view of column 10, lines 56-63 and column 3, line 13.

With respect to dependent claim 45, the first target analyte in the method of Pinkel *et al.* is an oligonucleotide (column 4, line 65 to column 5, line 1).

With respect to dependent claim 47, the increase in signal-to-noise ratio using the method of Pinkel *et al.* is inherent in (necessarily follows from) the identity of the apparatus and method of operation.

With respect to dependent claim 48, the sensor array **14** provided in the method of Pinkel *et al.* comprises a fiber optic bundle.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel *et al.* (US005690894A).

With respect to dependent claim 46, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the baseline of fluorescence signals in the method of Pinkel *et al.* because the detector system may be employed with a computerized data

acquisition system and analytical program (column 12, lines 10-22) and such an adjustment (calibration) is a known and useful step in accurately measuring responses.

9. Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel *et al.* (US005690894A) in view of Lough *et al.* (US005900481A).

With respect to dependent claim 41, the sensor elements in the method of Pinkel *et al.* do not comprise beads, but are instead the ends **11** of the fiber strands **10** which may have a specific shape (column 7, line 56 to column 8, line 3). Lough *et al.* shows that beads are known (Fig. **1**) as elements in a sensor array (column 5, lines 62-67). The beads of Lough *et al.* are suitable for the types of binding molecules used and fluorescent signals measured in the sensor array **14** of Pinkel *et al.* and further provide the convex surface Pinkel *et al.* identifies as advantageous. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Pinkel *et al.* to specify that the sensor ends **11** therein were bound to beads as suggested by Lough *et al.* (as the fiber strands **10** in Pinkel *et al.* qualify as a support as described by Lough *et al.* at column 3, line 29).

With respect to dependent claim 42, the sensor elements in the method of Pinkel *et al.* do not comprise beads, but are instead the ends **11** of the fiber strands **10** which may have a specific shape (column 7, line 56 to column 8, line 3). Lough *et al.* shows that beads are known (Fig. **1**) as elements in a sensor array (column 5, lines 62-67). The beads of Lough *et al.* are suitable for the types of binding molecules used and fluorescent signals measured in the sensor array **14** of Pinkel *et al.* and further provide the convex surface Pinkel *et al.* identifies as advantageous. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Pinkel *et al.* to specify that the sensor ends **11** therein were bound to beads as suggested by Lough *et al.* (as the fiber strands **10** in Pinkel *et al.* qualify as a support as described by

Lough *et al.* at column 3, line 29). The connection of the beads suggested by Lough *et al.* and the sensor ends **11** in the sensor array **14** provided in the method suggested by Pinkel *et al.* is a choice within the ordinary skill in the art at the time the invention was made. The specification of "wells" would have been obvious in view of the mechanical advantage afforded thereby in retaining the suggested beads to the faces of the fiber optic strands **10** and the knowledge from Lough *et al.* at column 3, lines 35-37 that beads in pits (functionally equivalent to the recited wells) are known.

Response to Submission(s)

10. The amendment filed September 4, 2001 has been entered.

11. Applicant's arguments filed September 4, 2001 have been fully considered but they are not persuasive.

The contention that a detector arranged to read the signal from groups of optical fibers **10** where all of the optical fibers **10** in a group bear the same species of biological binding partner will then individually evaluate the signal from each fiber in that group is unpersuasive. The evaluation is performed at the level of the biological binding partner in the aggregate and the contribution of the individual fibers to the group signal is a summation especially since there is no preservation of a fixed spatial relationship between any of the transmission ends **12** in a group of optical fibers bearing a particular biological binding partner. More preferably, Pinkel *et al.* writes, a CCD element or phototube is used to detect a signal representing the binding of a single species of biological binding partner present at the sensor face **13** of the optical fiber array **14**, that is, the signals from individual fibers are summed to create a signal representing the binding of the particular partner regardless of which fiber it bound to. As for the alleged technical difficulty in measuring individual signals from individual optical fibers in a group, it must be noted that the disclosure of Pinkel *et al.* is entirely adequate to measure individual signals from individual optical fibers **10**, especially since in the

extreme case the signal for each optical fiber comprising the optical fiber array **14** can be individually focused on detector(s) **20**. Accordingly, the presence of the fibers in a group is no barrier to those skilled in the art using the disclosure of Pinkel *et al.* to measure individual signals from individual optical fibers in a group. See column 11, lines 61-63.

For at least the reasons explained above, Applicant is not entitled to a favorable determination of patentability in view of the arguments submitted September 4, 2001.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Constantine Hannaher whose telephone number is (703) 308-4850. The examiner can normally be reached on Monday-Friday with flexible hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Seungsook (Robin) Ham can be reached on (703) 308-4090. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722 for regular communications and Not Established for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

ch
November 2, 2001

Constantine Hannaher
Primary Examiner